

## REMARKS

Entry of the above amendments in reconsideration of this application are respectfully requested. Upon entry of the amendments, this application will contain claims 36-60 and 62-65 pending and under consideration. It is believed that the above amendments and the following remarks comprehensively address all outstanding rejections in the application. Accordingly, reconsideration and allowance of the application are requested.

Claims 54-60 and 62 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 54-60 and 62 also stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Independent claim 54 has been amended to specify the bonding techniques identified in the application. Support for such an amendment can be found in the present application at, for example, paragraph [0069]. One skilled in the art would be able to form the claimed devices based on these bonding techniques without any undue experimentation. Claims 55-60 and 62 each depend from claim 54 and thus include this limitation as well. Accordingly, it is believed that claims 54-60 and 62 are fully supported in the application so as to enable one skilled in the art to make and use the claimed implantable biomaterial devices. Withdrawal of these rejections is thus respectfully requested.

Claims 36-44 stand rejected under 35 U.S.C. §103 as being unpatentable over Voytik-Harbin et al. (U.S. Patent No. 6,444,229) in view of Stinson et al. (U.S. Patent Application No. 2004/0111149). The Examiner alleges that Voytik-Harbin et al. generally teach the claimed injectable chemotherapeutic composition but for the inclusion of a radiopaque powder material, which the Examiner contends is taught by Stinson et al. Applicant respectfully disagrees.

Independent claim 36 requires that the bioabsorbable collagenous biomaterial be provided in an “injectable, viscous gelatin suspension...” The Examiner contends that Voytik-Harbin et al. generally teach this feature. However, Voytik-Harbin et al. do not teach a gelatin suspension as claimed. The present application teaches that an injectable material “can be readily made by comminuting the invention 5 into small fibrils, fragments, or the like, then suspending them in solution, such as, but not limited to, a biocompatible gelatin suspension.” See paragraph [0089]. This is in no way the same as the gel taught by Voytik-Harbin et al. Indeed, Voytik-Harbin et al. teach the formation of a gel by digesting a submucosal tissue and raising the pH by the addition of “a buffer that does not leave a toxic residue, and has a physiological ion concentration and the capacity to hold physiological pH. Examples of suitable buffers include PBS, HEPES, and DMEM.” See Voytik-Harbin et al. at column 7, line 64 through column 8, line 2.<sup>16</sup> Voytik-Harbin et al. also teach the addition of an acid or a base to adjust the pH to a desired level. Voytik-Harbin et al. never teach or suggest providing a bioabsorbable collagenous biomaterial in an injectable, viscous gelatin suspension as required by independent claim 36. Claims 37-44 depend from claim 36 and are thus believed to be patentable over Voytik-Harbin et al. in view of Stinson et al. for at least the same reasons. Withdrawal of this rejection is respectfully requested.

Claims 45-53 stand rejected under 35 U.S.C. §103 as being unpatentable over any of Kropp (Urology, 1995), Whitson (U.S. Patent No. 5,997,575) and Bonadio (U.S. Patent No. 5,942,496) in view of Stinson et al. Similarly, claims 45-53 and 63-65 stand rejected under 35 U.S.C. §103 as being unpatentable over any of Badylak et al. (WO 96/24461), Badylak 2 (WO 96/25179), Cook et al., (WO 98/22158), Fearnott (U.S. Patent No. 6,358,284), Badylak 3 (U.S. Patent Application No. 2004/0078076) in view of Stinson et al. In each case, the

Examiner contends that while the cited references do not specifically teach a coil, because they teach a variety of other shapes, it would have been obvious for one of ordinary skill in the art as a matter of design choice to construct a coil-shaped device. Applicant respectfully disagrees.

As previously indicated, none of the cited references teaches a bioabsorbable collagenous biomaterial formed into the shape of a coil as required by independent claim 45. A coil finds particular advantages not recognized by the design shapes taught by the cited references. For example, a braided coil structure can be unwound or crumpled to facilitate delivery via a catheter. Once at the desired site of implantation, the coil can form back into its coiled shape. See, for example, the present application at paragraph [0091]. The Examiner indicates that Whitson teaches “flat plates but they can also include other shapes such as screens, opposed cylinders or rollers and complementary nonplanar surfaces” (col. 6, lines 5-10 or “hollow sphere or pouch”, (col. 7, line 22). This reference, as well as any of the other cited references, in no way teaches or suggests the formation of a coiled structure. A coil will generally be formed in an entirely different manner than the shapes taught by the cited references. For example, a coil can be formed as a braided or non-braided structure. In either case, the material can be wound around a mandrel to form a coil. Thus, one skilled in the art would not have been motivated to form a coiled structure since the technique required to form such a structure and the advantages of such a structure are lacking in the teachings of the cited references. Moreover, because a coil differs both structurally and functionally from the shapes of the reference, it is improper to allege that it is merely a design choice. See In re: Chu, 36 U.S.P.Q. 2d, 1089 (Fed. Cir. 1995). Claims 46-53 and 63-65 each depend from

claim 45 and thus believed to be patentable for at least the same reasons. Accordingly, withdrawal of these rejections is respectfully requested.

In view of the foregoing amendments and remarks, reconsideration and allowance of this application containing claims 36-60 and 62-65 is requested. The Examiner is requested to telephone the undersigned attorney if the Examiner believes that any rejection remains applicable to the claims of the application, so that the undersigned attorney can be afforded an opportunity to telephonically or personally interview the Examiner prior to the next Office Action.

Respectfully submitted,

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